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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,454	08/29/2001	Dietrich A. Stephan	64688/153	5061

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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,454	STEPHAN ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-25 is/are rejected.
- 7) ☒ Claim(s) 18, 21 and 23 is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 page</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 18-25 in the reply filed on September 9, 2004 is acknowledged. The traversal is on the ground(s) that if claims 18-25 are found to be allowable, claims 1-17 will be rejoined with claims 18-25. This is not found persuasive because the practice of claim 18 does not require the method steps recited in claim 1. The method recited in claim 18 is directed toward inhibiting or reversing *in vivo* metastasis in a M+ class tumor by administering an inhibitor of the upregulation of a gene associated with the M+ class. Although the instant claim recites "gene identified by claim 1", the instant claim's scope includes all genes associated with a M+ class tumor regardless of the method of identification or discovery. Thus, Group I and II are separate inventions, neither of which requires the practice of the other. Claims 1-17 will not be rejoined with claims 18-25, even if claims 18-25 and their successors are found allowable.

2. Claims 1-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 9, 2004.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The abstract of the disclosure is objected to because the abstract is over 150 words. In addition, the abstract must also be supplied on its own separate sheet of paper. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities: misspellings and typographical errors around found in the specification. For example, p. 1, line 18 "Children's" is misspelled. Appropriate correction is required
5. Claim 21 objected to because of the following informalities: Claim 21 recites a method of using the inhibitor TLK 886 for inhibiting *in vivo* metastasis. However, there is nothing in the specification that mentions TLK 886. The specification does mention using TLK 286. For purposes of examination, the Examiner will assume that applicant meant to recite TLK 286. Appropriate correction is required.
6. Claim 23 objected to because of the following informalities: Claim 23 recites a method of using the inhibitor SCH88336 for inhibiting *in vivo* metastasis. However, there is nothing in the specification that mentions SCH88336. The specification does mention using SCH66336. For purposes of examination, the Examiner will assume that applicant meant to recite SCH66336. Appropriate correction is required.

Claim Objections

7. Claim 18 is objected to because of the following informalities: "metastasis" is misspelled in line 1 in the instant claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

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8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

10. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

11. Claims 18-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim(s) also contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

12. Claim 18 is directed toward inhibiting or reversing *in vivo* metastasis in a M+ tumor in a subject. However, the specification does not enable one of skill in the art to perform any method of inhibiting or reversing *in vivo* metastasis in a M+ tumor in a subject. Although the specification describes *in vitro* methods, the *in vitro* methods are not an adequate substitute to describe *in vivo* methods. Administering chemical compounds *in vivo* is highly unpredictable, because once a compound is introduced into an organism, the compound is subject to a variety of factors which may cause unexpected results. In addition, the specification does not supply any type of correlation between the *in vitro* methods described and the *in vivo* methods claimed. Collett et al. discusses major obstacles with correlating *in vitro* methods to *in vivo* methods as well as difficulties with introducing chemical compounds *in vivo* (p. 819, columns 1-2, Introduction; p. 823, column 1, under Discussion to p. 824, column 1, first full paragraph). Thus, without a clear description of the instant method, one skilled in the relevant art could not determine if the inventor, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 18, 20, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Zujewski et al.

15. Regarding claims 18 and 20, Zujewski et al. teach a method of administering *in vivo* to a subject an effective amount of an inhibitor of an upregulation of a gene associated with an M+ class tumor (p. 930, column 1, last paragraph; p. 938, column 1, first paragraph). Zujewski et al. also recommend the effective amount for an effective period of time for administering an inhibitor of an upregulation of a gene associated with an M+ class tumor (p.939, paragraph bridging column 1 and 2).

16. Regarding claims 21-22, Zujewski also uses the R115777 compound as the inhibitor of the upregulation of as genes associated with M+ class tumors (p. 940, column 1 and 2). Zujewski et al. also recommend the effective amount for an effective period of time for administering R115777 (p.939, paragraph bridging column 1 and 2).

17. Claims 18-21 and 23 - 25 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Daley.

18. Regarding claims 18 and 19, Daley teaches a method of administering *in vivo* to a subject an effective amount of a neutralizing antibody of an protein encoded by an

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upregulated gene associated with an M+ class tumor, such as a Ras signaling pathway inhibitor (column 04, lines 55-68). Daley teaches applying these methods to metastatic tumors (column 42, lines 31-37). Daley also teaches administering an effective amount for an effective period of time an inhibitor of a gene associated with M+ class tumors (column 41, line 57 – column 42, line 57).

19. Regarding claims 18 and 20, Daley teaches a method of administering *in vivo* to a subject an effective amount of a chemical inhibitor of an upregulation of a gene associated with an M+ class tumor, such as a Ras signaling pathway inhibitor (column 41, lines 11-29). Daley teaches applying his method to metastatic tumors (column 42, lines 31-37). Daley also teaches administering an effective amount for an effective period of time an inhibitor of a gene associated with M+ class tumors (column 41, line 57 – column 42, line 57).

20. Regarding claims 21 and 23-25, Daley teaches administering SCH66336, U0126 and STI-571 to a subject (column 41, lines 11-29). Daley also teaches administering an effective amount for an effective period of time an inhibitor of a gene associated with M+ class tumors (column 41, line 57 – column 42, line 57).

Claim Status

Claims 1-25 pending.

Claims 1-17 withdrawn from consideration.

Claims 18-25 rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:30-7:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JL

Ardin H. Marschel 12/21/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER